December 4, 2019

GS Medical Co., Ltd.
% Barry Sands
President
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, Massachusetts 01860

Re: K192335
Trade/Device Name: TRACKER Kyphoplasty System
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone bement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: November 6, 2019
Received: November 12, 2019

Dear Mr. Sands:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura Rose, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair,
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192335

Device Name
TRACKER Kyphoplasty System

Indications for Use *(Describe)*
The TRACKER Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

GS Medical 's TRACKER Kyphoplasty System 510k Submission

I. SUBMITTER

GS Medical Co. Ltd.
90, Osongsaengmyeong 4-ro
Osong-eup, Cheongwon-gun
Chungcheongbuk-do 363-951
Korea

Phone: 352.327.4641
Fax: 352.378.2617

Contact Person:
Barry Sands
RQMIS, Inc.
110 Haverhill Road, Suite 526
Amesbury, MA 01913
Phone: +1 (978) 358-7307
Fax: +1 (978) 477-0206

Date Prepared: 14 November 2019

II. DEVICE

Trade/Device Name:	TRACKER Kyphoplasty System
Common or Usual Name:	Inflatable Bone Tamp
Classification Name:	Orthopedics
Regulation Number:	21 CFR 888.3027
Regulatory Class:	Class II
Product codes	NDN, HRX

III. PREDICATE DEVICES

Primary Predicate

Device	Manufacturer	FDA Number
Medinaut Kyphoplasty System	Imedicom Co. Ltd.	K153296

Secondary Predicate

Device	Manufacturer	FDA Number
Medinaut Kyphoplasty System	Imedicom Co. Ltd.	K133669

IV. DEVICE DESCRIPTION

Indications for Use:

The TRACKER Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.

Description:

The TRACKER Kyphoplasty System (KS) comprises the TRACKER-X, P (GSK System) and the TRACKER-I (GCD System). The TRACKER-X, P and the TRACKER-I System are packaged in their own containers and are then packaged together in a TRACKER Kyphoplasty System container.

The TRACKER-I System is sold only as a System. The individual System Accessories are not sold separately.

The GSK System consists of the TRACKER-P balloon expander and the TRACKER-X balloon catheter. The TRACKER-I is a cement dispenser kit intended for percutaneous access to bone and delivery of bone cement.

V. SUBSTANTIAL EQUIVALENCE

Technological Comparison

As explained in the 510(k) submission, the TRACKER Kyphoplasty System is substantially equivalent to other legally marketed inflatable bone tamps. Specifically, the TRACKER Kyphoplasty System is substantially equivalent to MEDINAUT Kyphoplasty System. As explained in more detail in the 510(k) submission, the TRACKER Kyphoplasty System has the same general intended use, indications, technological characteristics, and principles of operation as the previously cleared primary predicate MEDINAUT Kyphoplasty System (K153296). The TRACKER Kyphoplasty System also has the same general intended use, technological characteristics, and principles of operation as the previously cleared additional predicate MEDINAUT Kyphoplasty System (K133669).

Performance Comparison

In all instances the device functioned as intended and all results were satisfactory and met all performance specifications. The tests performed were:

- Balloon Deflation
- Burst Pressure
- Fatigue Strength

- Unconstrained Burst Strength
- Inflated Dimension
- Insertions and Withdrawal Force
- Tensile Bond

Comparison to the Predicate Device

	Subject Device	Predicate Device	Predicate Device
Device Name	TRACKER Kyphoplasty System	MEDINAUT Kyphoplasty System	MEDIANUT Kyphoplasty System
510k Number	-	K133669	K153296
Manufacturer	GS Medical Co., Ltd.	IMEDICOM Co., Ltd.	IMEDICOM Co., Ltd.
Product Code	HRX, NDN	HRX, NDN	HRX, NDN
Common Name	Inflatable Bone Tamp	Inflatable Bone Tamp	Inflatable Bone Tamp
Indications for Use	The TRACKER Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.	The MEDINAUT Kyphoplasty System is intended to be used for the reduction of fracture and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal Polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation procedures, such as kyphoplasty.	The MEDINAUT Kyphoplasty System is intended to be used for the reduction of fractures and/or creation of a void in cancellous bone in the spine, tibia, radius, and calcaneus. This includes percutaneous vertebral augmentation. The system is to be used with cleared spinal polymethylmethacrylate (PMMA) bone cements indicated for use during percutaneous vertebral augmentation, such as kyphoplasty.
Components	- Bone Catheter - Expander Syringe - Kit (Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire	- Bone Catheter - Expander Syringe - Kit (Needle Pipe, Needle Pin, Expander, Cannula, Spacer, Guide Wire, Wire Pin, Cement Pusher,	Same as Primary Predicate Device(K133669)

	Pin, Cement Pusher, Cement Filler, and Guide wire)	Cement Filler, and Guide wire)	
Balloon Size	10mm, 15mm, 20mm	10mm, 15mm, 20mm	Same as Primary Predicate Device(K133669)
Bone Tamp Max. Inflation Pressure	350 PSI	350 PSI	Same as Primary Predicate Device(K133669)
Composition of Material	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS	Thermoplastic Polyurethane Platinum Polycarbonate & ABS Stainless Steel & ABS	Same as Primary Predicate Device(K133669)
Packaging	Pouch, Tyvek Blister Tray, Cardboard Box	Pouch, Tyvek Blister Tray, Cardboard Box	Same as Primary Predicate Device(K133669)
Biocompatibility	Meets ISO 10993	Meets ISO 10993	Same as Primary Predicate Device(K133669)

VI. NON-CLINICAL TESTING

- Sterilization validation testing has been performed in accordance with ISO 11138-2 and ISO 11135-1 and ISO 1422.
- The tests to validate the shelf life of the device were conducted and the test results validated 3-year shelf life. (ASTM F 1980)
- Biocompatibility tests were performed in accordance with ISO 10993-1, 5, 7, 10, 11. These tests included:
    - Test for *in vitro* cytotoxicity
    - Skin Sensitization test
    - Intracutaneous Reactivity test
    - Acute Systemic Toxicity test
    - Pyrogen test

  All biocompatibility tests met endpoints required by ISO 10993.

VII. CONCLUSION

The TRACKER Kyphoplasty System is as safe and effective as the MEDINAUT Kyphoplasty System (K153296). The TRACKER Kyphoplasty System has the same intended uses and indications, technological characteristics, and principles of operation as its predicate device. Performance data demonstrate that the TRACKER Kyphoplasty System is as safe and effective

as the MEDINAUT Kyphoplasty System. Thus, the TRACKER Kyphoplasty System is substantially equivalent.